OSD-TST-01 Version: 01 Page 1 of 7

STANDARD OPERATING GUIDELINES: EVIDENTIAL BREATH ALCOHOL TESTING

1 Scope

To describe evidential breath alcohol testing policies and procedures for instrument certification, testing location management, record keeping, electronic data management, record retention and release, and Technical Supervisor proficiency testing.

Any changes which occur as a result of the implementation of these Guidelines apply only to breath tests that are done on or after the effective date of this document. These procedures were adapted for accreditation purposes from those previously determined by the Scientific Director to be valid for use. Previous policies are not nullified and nothing herein should be construed as limiting or canceling the effect of old policies on tests done under these previous policies.

2 Definitions

- **Adjustment** a set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of the quantity to be measured.
- Calibration A procedure that establishes the accuracy, precision, uncertainty of measurement and linear response of a breath alcohol measuring instrument by the measurement of known standards. It is not defined as any other action to repair, adjust, clean, autocal or test an instrument. These actions are maintenance and are not part of the calibration procedure.
- Combined uncertainty The standard deviation of the result of a measurement when the result is obtained from the values of a number of other quantities. It is obtained by combining the individual standard uncertainties using the "root-sum-of-squares" method. Combined uncertainty shall be reported at approximately the 99.7% level (k=3) to four digits (rounded) after the decimal point.
- Lot A large volume of ethanol reference material that is mixed in a single container and considered to be uniform in ethanol concentration once the material is divided into smaller containers.
- **Lot number** A unique designator to document the preparation, analysis and traceability of a reference material or standard.
- NIST United States National Institute of Standards and Technology
- Nominal value The rounded or approximate value of a characterizing quantity of a measuring instrument or measuring system that provides guidance for its appropriate use. The nominal value of a Solution Lot shall be reported to three digits after the decimal point. Example: 0.080 g/210 L
- Office of the Scientific Director (OSD) The entity created by the Texas
 Department of Public Safety to carry out the provisions of Texas
 Administrative Code Title 37 Chapter 19 Breath Alcohol Testing Regulations.
 The Office of the Scientific Director provides certified reference materials and approves calibration procedures for forensic breath alcohol testing instruments.

Effective Date: 09/27/2013

OSD-TST-01 Version: 01 Page 2 of 7

- **Reference material** A homogenous and stable material sufficiently characterized with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.
- **Simulator** A device designed to heat an aqueous solution to a known temperature, used to deliver a vapor sample, usually ethanol, to a breath alcohol testing instrument for the purposes of calibration, calibration adjustment and/or calibration verification.
- **Technical Supervisor** A forensic scientist certified by the Office of the Scientific Director pursuant to the provisions of Texas Administrative Code Title 37 Chapter 19. A certified technical supervisor authorized to perform work in the calibration laboratory is by definition a calibration and reviewing analyst.
- **Traceability** The property of a measurement result whereby it can be related to a national authoritative standard through an unbroken chain of comparisons with each level having estimated uncertainties.
- **Vapor concentration** The ethanol concentration in the headspace above a dilute ethanol aqueous solution held at a known temperature, expressed in g/210 L.

3 Evidential Breath Alcohol Instrument Certification

- A. Prior to being placed into evidential service an instrument must have an embossed seal Evidential Breath Alcohol Testing Instrument Certificate issued by the OSD or an embossed seal instrument certification letter signed by the Scientific Director.
- B. An embossed seal Evidential Breath Alcohol Testing Instrument Certificate (Instrument Certificate) shall be issued by the OSD in conjunction with the issuance of an instrument's first Evidential Breath Alcohol Testing Instrument Calibration Certificate (Calibration Certificate). Issuance of a Calibration Certificate is described in The Standard Operating Guidelines: Evidential Breath Alcohol Instrument Calibration (OSD-CAL-01). Additional Instrument Certificates will not be issued when subsequent Calibration Certificates are submitted for an instrument.
- C. The calibration procedure described in The Standard Operating Guidelines: Evidential Breath Alcohol Instrument Calibration (OSD-CAL-01) shall be performed under any of the following conditions:
 - 1. Prior to an instrument being placed into evidential service for the first time.
- 2. The instrument has undergone a calibration adjustment on or after the effective date of this revision.
- 3. As determined by the Technical Supervisor.

4 Instrument and Testing Location Management

- A. An official inspection by a Technical Supervisor may only be conducted at the evidential testing location. Each part of the inspection shall occur at the testing location and includes not only the instrument, but the associated equipment and the testing environment as a whole.
 - The capability of the instrument to detect and subtract the effect of acetone shall be tested.

OSD-TST-01 Version: 01 Page 3 of 7

A Technical Supervisor shall conduct a printed ACA test and introduce acetone sufficient to cause the instrument to flag the test as an interferent while producing a reference result of 0.000.

- A Technical Supervisor shall conduct a breath test in the normal subject testing mode used for evidential testing. The subject last name for this test is **INSP TS**. In order for an **INSP TS** test to be considered properly completed the test record must have all of the following:
 - a) No invalid messages printed on the test record.
 - b) All results clearly printed.
 - c) All air blank results must be 0.000.
 - d) Subject results must be 0.000.
 - e) The signature of the Technical Supervisor.
- 3. A Technical Supervisor may conduct additional tests or checks of the instrument and simulator as he/she deems necessary.
- B. An official inspection (as described in Section 4.A) shall be performed by a Technical Supervisor each time an instrument is placed into or returned to service at a testing location.
- C. Each time an instrument is placed into or returned to service at a testing location, a Technical Supervisor shall document on the **INSP TS** test record the:
 - 1. Date on which the instrument was originally certified.
- 2. Date on which the instrument calibration was last adjusted.
- 3. Date on which the last Calibration Certificate was issued.
- D. If possible, an official inspection (as described in Section 4. A) shall be performed each time an instrument is removed from service at a testing location.

If an official inspection is not performed when an instrument is removed from service, the Technical Supervisor shall make a written report noting the reason(s) an official inspection was not performed and the report shall be placed in the **Maintenance File**.

- E. Each active testing location should have an official inspection (as described in Section 4. A) personally conducted by a Technical Supervisor at least once per calendar month.
- F. At least once per calendar month the reference solution at each active evidential testing location should be replaced with a new solution and the lot number of the solution should be recorded on the test record.

The result of an analysis of a reference solution conducted on a certified instrument at an evidential testing location must agree within ± 0.01 g/210 L of the predicted value.

G. Should an official inspection (as described in Section 4. A) of an active instrument location not be completed during a calendar month, the tests conducted during that month shall not be automatically invalidated.

OSD-TST-01 Version: 01 Page 4 of 7

The Technical Supervisor shall make a written report to the appropriate Regional Manager and the OSD explaining why the instrument inspection was not completed and a determination as to the validity of the tests conducted at the location shall be made by the OSD.

H. A certified Technical Supervisor may conduct an evidential subject test if the need arises. A certified Technical Supervisor is not required to maintain a separate certification as a breath test operator.

5 Record Keeping: Instrument Certificate File, Solution File, Subject File and Maintenance File

- A. Evidential Breath Alcohol Testing Instrument Certificates and Letters of Certification shall be kept in the **Instrument Certificate File**.
- B. Records pertaining to reference solutions used at evidential testing locations shall be kept in the **Solution File**.

These documents shall include, but are not limited to, the Certificate of Analysis and documents necessary to establish the NIST traceability, vapor concentration, nominal value and the combined uncertainty of the reference solution.

- 1. The predicted value of the reference shall be the nominal value of the solution.
- 2. The nominal value of a reference solution shall be within ±0.003 or 3%, whichever is greater, of the vapor concentration of the alcohol concentration in g/210 L as traceable to NIST.
- 3. The vapor concentration and uncertainty of the alcohol concentration of the solution shall be determined via a procedure establishing traceability of measurement through an unbroken chain of comparisons to the National Institute of Standards and Technology (NIST), all having stated uncertainties.
- C. The Technical Supervisor is a custodian of evidential breath test records. These records shall be kept in the **Subject File**.
 - 1. Evidential subject test records contain a sequential test record number and are generated only when the instrument is in evidential service in an approved testing location.
- 2. No alterations shall be made to the data on a printed subject test record.
- 3. If a test record is missing from the **Subject File**, the Technical Supervisor shall make a reasonable effort to retrieve the missing record. If the record is permanently lost, then the record shall be replaced with the following information:
 - a) A non-evidential test record data printout generated from the database, if available.
 - b) A written explanation from the operator describing the reason for the lost record, if available.
 - c) Documentation of any other actions taken by the Technical Supervisor in relation to the missing record, if necessary.
- 4. Test records produced in a laboratory are not evidential and shall <u>not</u> be kept in the **Subject File**.

- OSD-TST-01 Version: 01 Page 5 of 7
- D. Records pertaining to instrument and simulator maintenance and repairs shall be kept in the **Maintenance File**.
 - 1. Maintenance records shall be organized and detailed enough to allow another Technical Supervisor to render an opinion in potential litigation concerning the maintenance history of any instrument.
- 2. The **Maintenance File** shall contain a copy of each **INSP TS** performed on each certified instrument (as described in Section 4.A.2).
- 3. The **Maintenance File** shall contain a copy of each ACA test record generated as a part of an official inspection to demonstrate the ability of the instrument to detect and subtract acetone performed on each certified instrument (as described in Section 4.A.1).
- 4. For each instrument, the **Maintenance File** shall contain notes regarding:
 - a) all components that are replaced or repaired
 - b) the adjustment of the calibration
 - c) the adjustment of the flow sensor
 - d) the cleaning of internal components including, but not limited to, the sample chamber and solenoids
- 5. If abbreviations or codes are used to document instrument maintenance and repairs, the **Maintenance File** shall contain a document clearly defining all abbreviations or codes used.
- 6. The **Maintenance File** shall contain notes regarding all components of each simulator that are replaced or repaired.
 - If abbreviations or codes are used to document simulator maintenance and repairs, the **Maintenance File** shall contain a document clearly defining all abbreviations or codes used.
- 7. The **Maintenance File** shall contain any other documents kept in the normal course of business by the Technical Supervisor regarding the maintenance of certified instruments and simulators.

6 Electronic Data Management

A. While the electronic data is not evidential, it is a powerful management tool and invaluable to the Texas Breath Alcohol Testing Program. It allows Technical Supervisors and the Office of the Scientific Director to monitor tests, operators and instruments. The data is extremely useful in the operator certification renewal process as well as for statistical analysis. The TS Monthly Activity Report, which is generated from Technical Supervisor instrument inspection data, is used by the Office of the Scientific Director to monitor required Technical Supervisor duties. To be useful the data must be standardized, accurate and complete. The Technical Supervisor shall assure that an electronic record exists in the database for each evidential subject record that is generated on an instrument. Data from tests that were not conducted in an approved evidential testing location shall not be kept in the subject test database.

- OSD-TST-01 Version: 01 Page 6 of 7
- 1. Instrument test data shall be transferred into the database management system via electronic means in all but the most exceptional circumstances.
- 2. Test record data shall be manually entered into the database only in the event of instrument inoperability or data loss. The Technical Supervisor shall make every attempt to repair the instrument sufficiently to allow electronic data transfer. Manual data entry shall be considered a last resort. Should all attempts at electronic data transfer fail, make written notification to the Office of the Scientific Director and the appropriate Regional Manager when tests are entered manually.
- B. The **TS Monthly Activity Report** records on-site maintenance inspections, reference solution changes, instrument data transfers to a Technical Supervisor's computer, and instrument data transfers to the Office of the Scientific Director for each Technical Supervisor Area.
- 1. The **TS Monthly Activity Report** is to be submitted by the end of each calendar month.
- 2. If the **TS Monthly Activity Report** is complete (no omissions) and does not require any additional information, press the send button in Black Mamba and then press the second send button, also in Black Mamba, to send the report.
- 3. If the **TS Monthly Activity Report** is missing data (has omissions) or requires additional information, a Technical Supervisor shall
 - a) Print the report and the memo that explains the missing data;
 - b) Scan the report, memo and all of the documents (INSP TS test records) necessary to reconcile the missing data into a single pdf document; and
 - c) <u>Email the pdf document to the appropriate Regional Manager, not</u> the OSD.
- 4. If a Technical Supervisor Area has more than one Technical Supervisor, all Technical Supervisors in the Area will be held equally responsible for the report.

7 Record Retention and Release

- A. Records in the Instrument Certificate File, Maintenance File, Solution File and Subject File shall be retained for 100 years. The records may be scanned into an electronic form (pdf) and/or retained in paper.
- B. Records shall be provided by the Technical Supervisor when requested through open records requests, discovery motions and subpoenas. A governmental record has the meaning assigned in Texas Government Code Sect. 552.002. Generally speaking, any document held in the possession of a Technical Supervisor is considered to be a government document. A record can be paper or electronic.
- C. Electronic data stored in the database known as Black Mamba shall not substitute for either printed evidential test records or evidential test records scanned into an electronic form. The breath alcohol test data stored in the database is insufficient to reproduce an evidential test. Air blank data is not stored and invalid tests produced during the last air blank appear valid in the database. Furthermore, the electronic data may be altered or fabricated entirely. For these reasons, it is recommended that only printed test records or

OSD-TST-01 Version: 01 Page 7 of 7

test records scanned into electronic form be submitted to comply with subpoenas, public open records requests and discovery motions. The Texas Breath Alcohol Testing Program recognizes only a printed or scanned test records as evidence of a breath alcohol test.

- D. Database printouts from Black Mamba do not always match the information contained on the actual printed test records. A disclaimer shall be included when database printouts are generated to comply with an open records requests, court orders and other such requests (as described in Section 7. F).
- E. Discovery motions signed by a judge and subpoenas shall be complied with by providing the actual printed or electronically scanned records contained in the subject and maintenance files, unless a judge specifically requires the Technical Supervisor to generate a database report. A disclaimer should be included when database printouts from Black Mamba are generated to comply with orders from a judge (as described in Section 7. F).
- F. When a database printout of breath alcohol data from Black Mamba is submitted to either the courts or to the public, the disclaimer included should state:

The information in this report is generated by a computer database. This data may not accurately reflect the information printed on evidential test records generated by the Intoxilyzer.

8 Proficiency Testing

- A. Once per calendar year all certified Technical Supervisors will be proficiency tested on their ability to prepare a solution of a concentration prescribed by the OSD.
- B. For each proficiency test, an email explaining the proficiency procedure will be provided to each Technical Supervisor being tested.
- C. The proficiency solution shall be approximately 500 mL and shall be submitted in a standard simulator solution bottle. The bottle shall be labeled with the Technical Supervisor's name and the date the solution was prepared.
- D. Proficiency solutions may be submitted in person, through common carrier or the equivalent.
- E. Proficiency solutions shall be analyzed by the OSD.
- F. To pass the proficiency test, the vapor concentration of the solution must be within ±0.0030 or 3%, whichever is greater, of that prescribed.
- G. Any Technical Supervisor who fails the first attempt will be asked to submit another proficiency solution and given a new deadline date for its submission. Any Technical Supervisor who fails the second attempt will be asked to come to the OSD to demonstrate their ability to prepare solutions and for remedial training, if necessary.

<u>Preparer</u>		
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Concurrence		
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